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I. INTRODUCTION

Discovery has revealed that Affymetrix, Inc. ("Affymetrix") has engaged in persistent and continuous efforts to mislead the United States Patent and Trademark Office in the prosecution of all of the patents asserted in this case. While issues of inequitable conduct are frequently factually intensive, Affymetrix's¹ conduct in conjunction with the prosecution of the '243 patent presents the type of clear-cut case of inequitable conduct that has been repeatedly found by courts to render the offending patents unenforceable. Affymetrix breached its duty of candor and good faith by intentionally withholding highly-material information generated during the course of litigation that involved a direct ancestor patent to the '243 patent. Affymetrix cannot credibly argue that the documents and information it intentionally withheld are not material to the claims of the '243 patent -- indeed courts have found such information to be material *per se* -- and thus inequitable conduct should be found as a matter of law.

First, Affymetrix failed to disclose even the *existence* of a prior litigation involving a directly-related patent to the '243 patent. This litigation involved allegations that the direct ancestor patent, U.S. Patent No. 5,445,934 ("the '934 patent") (which shares a specification with the '243 patent), was invalid and unenforceable. As a matter of settled case law, the existence of prior litigation involving the subject matter of a patent with the same specification was material *per se* to the patentability of the '243 patent and therefore had to be disclosed to the PTO. Yet Affymetrix intentionally failed to disclose even the existence of the prior litigation involving the '934 patent, let alone any of the pleadings or other materials generated in that litigation. The failure to disclose even the existence of this prior litigation constitutes inequitable conduct rendering the '243 patent unenforceable.

¹ The term "Affymetrix" as used herein encompasses inventors and prosecution counsel of the '243 patent associated with Affymetrix.

Second, while Affymetrix did at least disclose the existence of other less relevant litigation during the '243 prosecution, it did not inform or provide the PTO with key documents from these other litigations that go to the heart of (and indeed undermine) the patentability of the '243 patent. As a prime example, Affymetrix withheld a declaration in which the first named inventor of the '243 patent, Dr. Michael C. Pirrung, explained, under oath, why the methods of synthesizing nucleic acids disclosed in the specification of the '243 patent were not enabled in the relevant time frame. It goes without saying that a reasonable examiner would have considered this declaration highly material to the patentability of the claims of the '243 patent -- how much more material can a document get than the lead inventor saying the technology was not enabled at the time of filing? Furthermore, Dr. Pirrung's declaration undermines Affymetrix's arguments, made in the course of the prosecution leading to the '243 patent, that it was entitled to a priority date of at least March 7, 1990 (in an effort to preclude certain references as prior art). Affymetrix's intentional failure to disclose to the PTO the declaration of Dr. Pirrung (as one example of a host of other key documents) further constitutes inequitable conduct rendering the '243 patent unenforceable.

Affymetrix has intentionally breached clear-cut rules governing the prosecution of patents. Courts have found conduct less egregious than Affymetrix's here to justify a grant of summary judgment of inequitable conduct. Illumina thus respectfully requests that the Court find that Affymetrix's '243 patent is unenforceable as a matter of law due to inequitable conduct.

II. NATURE AND STAGE OF PROCEEDING

Plaintiff Affymetrix filed suit against Illumina on July 26, 2004. (D.I. 1) In its complaint, Affymetrix accuses Illumina of infringing U.S. Patent Nos. 5,545,531; 5,795,716; 6,355,432; 6,399,365; 6,607,887; and 6,646,243. Illumina filed its Answer and Counterclaims denying, *inter alia*, that its products infringe and counterclaiming that the asserted patents are

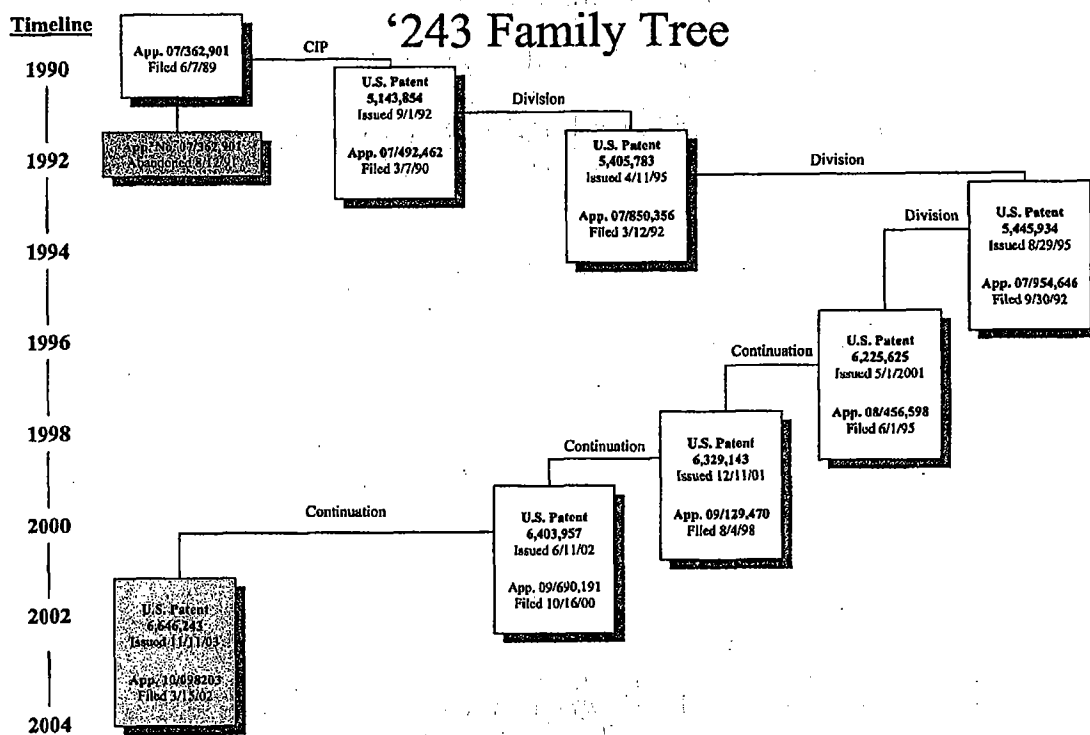
invalid under 35 U.S.C. §§ 102, 103 and 112. (D.I. 10) Illumina obtained leave to file and filed its Amended Answer and Counterclaims on February 17, 2006, adding, *inter alia*, allegations of unenforceability due to inequitable conduct. (D.I. 217) Subsequently, Affymetrix dismissed with prejudice one of the asserted patents -- U.S. Patent No. 6,607,887 -- from the litigation. (D.I. 266)

The parties have completed fact discovery and *Markman* briefing on disputed claim terms of the patents-in-suit. The parties will proceed with expert discovery following a claim construction ruling from the Court.

III. STATEMENT OF FACTS

A. Prosecution History of U.S. Patent No. 6,646,243

As shown below in the family tree of the '243 patent, the application that led to the



'243 patent, highlighted in yellow, was filed on March 15, 2002. The '243 patent is purportedly a continuation of several applications that issued as patents and ultimately a continuation-in-part of U.S. Application No. 07/362,901, which was filed on June 7, 1989. Affymetrix is claiming a priority date of March 7, 1990 for the '243 claims. (See Ex. A - Affymetrix's Supplemental Response to Illumina's 1st Set of Interrogatories). As shown, the application for the '243 patent is a continuation of a divisional application that issued as the '934 patent.

B. Affymetrix's Prior Patent Litigations

Affymetrix filed two patent infringement actions in 1998. The first of these two litigations, *Affymetrix, Inc. v. Synteni, Inc. and Incyte Pharmaceuticals, Inc.*, Civil Docket No. 98-cv-00006 GMS, was filed in the District of Delaware on January 6, 1998. (See Ex. B - 98-cv-00006 GMS docket). In this first case, Affymetrix alleged infringement of the '934 patent. (See Ex. C - Affymetrix's 1998 10-K SEC filing); (See Ex. D - Affymetrix's 2000 10-K SEC filing). The '934 patent is a direct ancestor of the '243 patent asserted in this case and they share the same specification.

The second case, *Affymetrix, Inc. v. Synteni, Inc. and Incyte Pharmaceuticals, Inc.*, Civil Docket No. 98-cv-00520 GMS, was filed in the District of Delaware on September 1, 1998. (See Ex. E - 98-cv-00520 GMA docket). In this case, Affymetrix alleged infringement of U.S. Patent No. 5,800,992 ("the '992 patent"), U.S. Patent No. 5,744,305 ("the '305 patent") and U.S. Patent No. 5,795,716 ("the '716 patent"). (See Ex. C).

In November of 1998, both cases were transferred to the Northern District of California. Civil Docket No. 98-cv-00006 GMS, which involved the '934 patent, acquired the case number 98-cv-4507 ("the 4507 litigation"). (See Ex. F - 4507 docket). Civil Docket No. 98-cv-00520 GMS, which involved the '992, '305 and '716 patents, acquired the case number 98-cv-4508 ("the 4508 litigation"). (See Ex. G - 4508 docket). On April 8, 1999, the 4507 litigation and the 4508

litigation were consolidated with all future case filings to be filed under the 4507 case number. (See Ex. F - 4507 D.I. 12).² The 4508 case ceased to exist as a separate case beyond that point. The 4507 litigation was ultimately dismissed with prejudice on December 21, 2001 after the parties settled. (See Ex. H at D.I. 666, 667). In the course of litigation, Incyte and Synteni alleged that the '934 patent was invalid. (See e.g., Ex. C at 41). Incyte and Synteni also included allegations that the '934 patent was unenforceable due to inequitable conduct. (See Exs. H at D.I. 213, 347, and 433).

At least Drs. Stephen Fodor and Lubert Stryer, named inventors of both the '934 and '243 patents, and Affymetrix's prosecution counsel who assisted in the prosecution of the '243 patent, can be shown to have been personally aware of the 4507 litigation. As CEO, Dr. Fodor signed SEC filings which disclosed the 4507 litigation. (See Exs. C). As a member of Affymetrix's Board of Directors, Dr. Stryer also signed SEC documents indicating his awareness of this litigation. (*Id.*).

C. Disclosure of Litigation Relating to Affymetrix's Patents

During the prosecution of the '243 patent, Affymetrix failed to disclose the *existence* of the 4507 litigation or that it had been in litigation with respect to the '934 patent, a direct ancestor of the '243 patent that shares the same specification. Instead, in an information disclosure statement dated May 30, 2002, Affymetrix *only* identified the 4508 litigation and other less relevant interference proceedings and litigations in an apparent attempt to misdirect the examiner with less relevant information. (See Ex. I - Initial Disclosure Statement dated 5/30/2002). For example, Affymetrix disclosed the existence of interference proceedings concerning the '992 and

² The consolidated 4507 litigation was reassigned on December 6, 1999 and proceeded as 99-cv-21164. (See Ex. H at D.I. 104). Affymetrix also failed to disclose this case number in addition to the 4507 case number during the prosecution of the '243 patent.

'305 patents. (*Id.* at IAFP00002186). It also identified other litigations involving the '992 and '305 patents, including, *Affymetrix v. Hyseq, Inc.*, Northern District of California, Civil Action No. C98 03192 FMS, *Affymetrix v. Synteni, Inc. and Incyte Pharmaceuticals, Inc.*, Northern District of California, Case No. C98-4508, and *Incyte Genomics, Inc. v. Affymetrix*, Northern District of California, Case No. C00-3210. (*Id.* at IAFP00002187). None of these proceedings involved a patent directly in the prosecution chain of the '243 patent.

Despite the fact that the 4508 and 4507 litigations were consolidated in April 1999 and reassigned in December 1999, the May 30, 2002 information disclosure statement only identified the 4508 litigation docket number. Affymetrix similarly withheld the 4507 litigation during the prosecution of the '143 and '625 patents. (*See* Ex. J, '143 File History at 9/26/00 Amendment; Ex. K at '625 File History at 8/24/00 Amendment after Allowance). Furthermore, although Affymetrix disclosed the existence of the 4508 litigation, it did not disclose to the PTO *any* documents from this litigation. Affymetrix *never* disclosed the 4507 litigation, or the fact that the validity and enforceability of a direct predecessor to the '243 patent was being challenged by Synteni and Incyte in that litigation. Affymetrix's pattern of selective disclosure and attempts to bury the examiner during the prosecution of the '243 patent also included providing the PTO with "multiple copies of two compact discs" containing prior art articles, patents and published applications on one hand, while at the same time failing to produce a *single page* from any of its litigations. (*See* Ex. I. at IAFP00002185). Despite their obvious relevance, Affymetrix withheld "litigation documents that may be of interest to the Examiner . . . due to the extensive nature of the multiple litigation and papers filed therein." (*Id.* at Ex. I, IAFP00002188).

In contrast to the prosecution of the '243 patent -- and as evidence of its intent to deceive the PTO while prosecuting the '243 patent -- Affymetrix *did disclose* the 4507 litigation during

the prosecution of U.S. Pat. No. 6,197,506 ("the '506 patent"), a patent that is not a direct descendant of the '934 patent. (See Ex. L - Initial Disclosure Statement dated 8/6/90). In fact, during the prosecution of the unrelated '506 patent, Affymetrix also disclosed Incyte's Initial Disclosure of Prior Art from the 4507 litigation, which details specific combinations of prior art references that anticipate or render obvious the claims of the '934 patent. (See Ex. M - Incyte's and Synteni's Initial Disclosure of Prior Art).

D. The Declaration of Dr. Michael C. Pirrung

To support their opposition to a preliminary injunction in the 4508 litigation, Incyte and Synteni filed a declaration on March 26, 1999 from Dr. Michael C. Pirrung ("the Pirrung declaration"), the lead inventor on both the '934 and the '243 patents. (See Ex. N - Pirrung Declaration). The Pirrung declaration describes why Affymetrix's Very Large Scale Immobilized Polymer Synthesis ("VLSIPS") method, a photolithographic synthesis method discussed in the specification of the '243 patent, was not enabled as of 1990. (*Id.* at ¶ 26-27). Specifically, Dr. Pirrung states in his declaration that

one of ordinary skill in the art as of 1990 could not prepare an array of oligonucleotides or polynucleotides, using the VLSIPS synthesis method described, that could be used for gene sequencing or gene expression monitoring applications.

(*Id.* at ¶ 27) (emphasis added).

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Dr. Pirrung provides several bases that support his statement. First, while photolithographic synthesis requires the use of photoremovable protecting groups, there were not known photoremovable groups which would work with photolithographic nucleic acid synthesis in 1990. (See Ex. N at ¶ 64). Specifically, in his declaration, Dr. Pirrung explains that "[d]eprotecting of protecting groups known in 1990 for alcohols required high energy radiation. Unfortunately, high energy radiation damages DNA." (*Id.* at ¶ 63).

Second, Dr. Pirrung explains that "there were numerous incorrect assumptions made about the applicability of conventional chemical DNA synthesis to photolithographic DNA synthesis." (*Id.* at ¶ 69). Dr. Pirrung elaborates on this point, saying

[T]herefore, by comparison to chemical DNA synthesis, a different bottom connection linker had to be found, a different side chain connection nucleoside protecting group had to be found, or a different process or mechanism to remove the auxiliary or side connection nucleoside protecting group without severing the bottom connection linker had to be found, in order to implement photolithographic DNA synthesis An effective alternative was apparently unknown to Affymetrix until sometime after 1990, as evidenced by their own publications.

(*Id.* at ¶ 58). Dr. Pirrung further discusses how the side chain protecting groups, such as benzoyl, that were used with chemical DNA synthesis did not work with photolithographic DNA synthesis. (*Id.* at ¶ 60, 63).

Affymetrix did not disclose the Pirrung declaration or any other litigation material from the 4508 litigation to the PTO during the prosecution of the '243 patent. Neither did Affymetrix inform the examiner that the lead inventor of the pending application had taken this position regarding the non-enablement of the invention. This allowed Affymetrix to advance arguments

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regarding the enablement of the VLSIPS™ method that it otherwise would not have been able to make, thereby preventing the PTO from accurately evaluating Affymetrix's claimed date of priority for the '243 patent. Specifically, in the specification of the '243 patent, Affymetrix suggests that the VLSIPS™ method enables the synthesis of high density arrays, while contending other conventional methods are not economically practical and are limited in the amount of chemical diversity they can generate. (See Ex. Q - '243 Patent, col. 2:19-63).

Similarly, in the chain of prosecution leading up to the '243 patent, the examiner rejected claims in light of PCT WO 89/10977 by Southern ("the '977 application"), whose U.S. equivalent is U.S. Patent No. 5,700,637 ("the '637 patent"). (See Ex. R - 11/22/99 Amendment and Response). The '977 application was published on November 16, 1989. In order to overcome this rejection, Affymetrix claimed priority to June 7, 1989, arguing that "*neither the Southern PCT or U.S. effective dates are prior art to Applicants [sic] first priority date.*" (*Id.* at IAFP00018449-9 (emphasis added)). Affymetrix could not credibly have claimed this first priority date (or the March 7, 1990 priority date it now claims) if it had given the Pirrung declaration to the PTO, since that declaration states that Affymetrix's method could not be used to manufacture nucleic acid arrays in 1990.

IV. SUMMARY OF APPLICABLE LAW

A. Summary Judgment

Summary judgment is properly granted where there are no genuine issues of material fact such that the moving party is entitled to judgment as a matter of law. *Paragon Podiatry Lab. v. KLM Lab., Inc.*, 984 F.2d 1182, 1184 (Fed. Cir. 1993). Summary judgment respecting a defense of inequitable conduct is appropriate where the criteria for summary judgment are satisfied. *Id.* at 1190; *Ferring B.V. v. Barr Lab., Inc.*, 437 F.3d 1181 (Fed. Cir. 2006) (affirming summary

judgment in favor of alleged infringer on grounds that the patent-at-issue was unenforceable due to inequitable conduct).

In summary judgment motions based on inequitable conduct, once the movant has made a *prima facie* case of inequitable conduct, the burden shifts to the patentee to come forward with evidence which would require reassessment of the validity of the defense and preclude summary judgment. *Ferring B.V.*, 437 F.3d at 1192 (quoting *Paragon Podiatry Lab.*, 984 F.2d at 1191). Those accused of inequitable conduct before the PTO cannot raise a genuine issue of material fact simply by submitting conclusory allegations or offering completely insupportable or conflicting explanations or excuses. *Ferring B.V.*, 437 F.3d at 1192-93.

B. Inequitable Conduct

All patent applicants owe a duty of candor and good faith to the PTO. *Purdue Pharma L.P. v. Endo Pharm., Inc.*, 438 F.3d 1123, 1128 (Fed. Cir 2006); 37 C.F.R. § 1.56(a) (1992). "A breach of this duty may constitute inequitable conduct, which can arise from a failure to disclose information material to patentability, coupled with an intent to deceive or mislead the PTO." *Bruno Indep. Living Aids, Inc. v. Acorn Mobility Svcs., Ltd.*, 394 F.3d 1348, 1351 (Fed. Cir. 2005).

A patent applicant's duty of candor and good faith is not limited to disclosing prior art; rather, a patent applicant must disclose all material information to the USPTO. *Critikon, Inc. v. Becton Dickinson Vascular Access, Inc.*, 120 F.3d 1253, 1258 (Fed. Cir. 1997); 37 C.F.R. § 1.56(a) (1992). Since violating this duty and committing inequitable conduct is "an offense against the PTO and the public," a finding of inequitable conduct renders an applicant's patent unenforceable. *Akron Polymer Container Corp. v. Exxel Container, Inc.*, 148 F.3d 1380, 1383 (Fed. Cir. 1998).

The first step in an inequitable conduct analysis is to determine if an applicant's conduct meets a threshold of (1) materiality and (2) intent to deceive or mislead the PTO. *Purdue Pharma L.P.*, 438 F.3d at 1128. If the movant proves inequitable conduct by clear and convincing evidence, the court balances the weight of the two factors to determine if an applicant's conduct is so culpable as to render the patent unenforceable. *Id.* "The more material the omission or the misrepresentation, the lower the level of intent required to establish inequitable conduct, and vice versa." *Pharmacia Corp. v. Par Pharm., Inc.*, 417 F.3d 1369, 1373 (Fed. Cir. 2005) (quoting *Critikon, Inc.*, 120 F.3d at 1256).

First, materiality of information can be judged under the "reasonable examiner" standard. *Aventis Pharma S.A. v. Amphastar Pharm., Inc.*, No. 05-1513, 2006 WL 925278, at *2 (Fed. Cir. April 10, 2006). Under this standard, information is material if a reasonable examiner would have considered it important in deciding whether to allow the patent application. *Id.*; *Digital Control Inc. v. Charles Mach. Works*, 437 F.3d 1309, 1314 (Fed. Cir. 2006). This standard is based on the definition of "materiality" in Rule 1.56 as it existed before 1992. *See* 37 C.F.R. § 1.56(b) (1991). In 1992, Rule 1.56 was revised.⁴ However, the revised rule "does not replace or supplant" case law applying the pre-1992 standard. *Digital Control Inc.*, 437 F.3d at 1316. Therefore, information is material if it meets either the reasonable examiner standard, or the revised Rule 1.56(b) standard. *Id.*

Second, to prove inequitable conduct, the defendant must show that the patentee intended to mislead or deceive the PTO. *Critikon, Inc.*, 120 F.3d at 1256. Intent rarely can be proven by

⁴ Under the 1992 Rule 1.56 standard, information may also be material when it is not cumulative to information already of record or being made of record in the application, and (1) It establishes, by itself or in combination with other information, a *prima facie* case of unpatentability of a claim; or (2) It refutes, or is inconsistent with, a position the applicant takes in: (i) Opposing an argument of unpatentability relied on by the Office, or (ii) Asserting an argument of patentability. 37 C.F.R. § 1.56(b) (1992).

direct evidence. *Ferring B.V.*, 437 F.3d at 1191. Accordingly, intent can be inferred where an applicant knew, or should have known, that the non-disclosed information would be material to the PTO's consideration of the patent application. *Critikon, Inc.*, 120 F.3d at 1256. An applicant facing "a high level of materiality and clear proof that it knew or should have known of that materiality, can expect to find it difficult to establish 'subjective good faith' sufficient to prevent the drawing of an inference of intent to mislead. . . ." *Id.* at 1257. Applicants cannot overcome the inference with "[a] mere denial of intent to mislead. . . ." *Critikon, Inc.*, 120 F.3d at 1257. This is especially true when the non-disclosed information is highly material. *Pharmacia Corp.*, 417 F.3d at 1373.

C. Duty to Disclose Related Litigation to the PTO

Failure to disclose the existence of a litigation involving the subject matter of a patent application being prosecuted and/or material documents arising from such a litigation can constitute inequitable conduct. *DaimlerChrysler AG v. Feuling Adv. Tech., Inc.*, 276 F. Supp. 2d 1054, 1064 (S.D. Cal. 2003) (holding that patentee committed inequitable conduct in not disclosing the existence of a litigation involving a parent patent during the prosecution of a continuation-in-part application); *Nisus Corp. v. Perma-Chink Systems, Inc.*, 421 F. Supp. 2d 1084, 1108-09 (E.D. Tenn. 2006) (holding that the patentee committed inequitable conduct in not disclosing the existence of a litigation involving the parent patent during the prosecution of a child patent).

Pursuant to the Manual of Patent Examining Procedure ("MPEP") § 2001.06(c), applicants *must* disclose -- there simply is no option -- the existence of a litigation involving the

subject matter of a patent application being prosecuted and any material documents arising from such litigation. MPEP § 2001.06(c)⁵ states:

Where the subject matter for which a patent is being sought is or has been involved in litigation, *the existence of such litigation and any other material information arising therefrom must be brought to the attention of the U.S. Patent and Trademark Office.* Examples of such material information include evidence of possible prior public use or sales, questions of inventorship, prior art, allegations of "fraud," "inequitable conduct," and "violation of duty of disclosure." Another example of such material information is any assertion that is made during litigation which is contradictory to assertions made to the examiner. *Environ Prods., Inc. v. Total Containment, Inc.*, 43 USPQ2d 1288, 1291 (E.D. Pa. 1997). Such information might arise during litigation in, for example, pleadings, admissions, discovery including interrogatories, depositions, and other documents and testimony.

MPEP § 2001.06(c) (emphasis added).

When an ancestor patent is involved in litigation, that litigation involves the same subject matter as any of its children. *DaimlerChrysler AG*, 276 F.Supp.2d at 1063 n.4 (patents that were continuations-in-part necessarily involved the same subject matter as an ancestor patent); *Nisus Corp.*, 421 F.Supp. 2d at 1104 (finding that litigation involving an ancestor patent was a related litigation involving the same subject matter as the child patent application).

The existence of a litigation involving the same subject matter as the application being prosecuted is material *per se*. *DaimlerChrysler AG*, 276 F.Supp.2d at 1063 ("Section 2001 refers to 'the existence of the litigation *and any other material* information.' (emphasis added). Thus, under the MPEP, litigation is material *per se*."); *Nisus Corp.*, 421 F.Supp.2d at 1104 ("Accordingly, 'related litigation' is *per se* material information covered by the duty of disclosure."); *ICU Medical Inc.*, 2005 WL 588341 at *14 ("In fact, related litigation is material

⁵ The MPEP does not have the force of law, but is entitled to notice as it is an official interpretation of statutes or regulations regarding an applicant's duty of disclosure during patent prosecution. *Molins PLC v. Textron, Inc.*, 48 F.3d 1172, 1180 n.10 (Fed. Cir. 1995); *ICU Medical, Inc. v. B. Braun Medical, Inc.*, No. C01-3202 CRB, 2005 WL 588341 at *13 (N.D. Cal. March 14, 2005); *Boehringer Ingelheim Vetmedica, Inc. v. Schering-Plough Corp.*, 68 F.Supp.2d 508, 548 (D. N.J. 1999).

per se."). The existence of litigation involving the subject matter of a pending patent application and documents arising from such litigation are so highly material that the PTO, through regulation and procedural rule, specifically requires the disclosure of this information. *Nisus Corp.*, 421 F. Supp.2d at 1106 (citing 37 C.F.R. § 1.56(b) and MPEP § 2001.06(c)).

Courts have repeatedly found that litigations relating to a patent with the same subject matter as an application being prosecuted are material to the prosecution of that application. *Boehringer Ingelheim Vetmedica, Inc.*, 68 F.Supp.2d at 551 ("The materiality of the concurrent [related patent] litigation which challenged both the validity and enforceability of the subject matter of the pending [related] application is obvious."); *DaimlerChrysler AG*, 276 F.Supp.2d at 1063 ("Moreover, in the prosecution of a continuation-in-part patent, the fact that the parent patent was the subject of litigation challenging its validity is clearly information that a 'reasonable [patent] examiner would consider [] important in deciding whether to allow the application to issue as a patent.'").

The failure to disclose litigation materials pursuant to MPEP § 2001.06(c) leads to a strong inference of intent.

The fact that [the patentee] did not provide the USPO, in writing, with the name of the pending case, its docket number, the district in which it was pending and this Court's conclusions, establishes a threshold showing of intent to deceive and a lack of good faith...Rather, given the [patentee's] failure to apprise the USPO of any of the substance of the [related] litigation, it is faced now with a negative inference of intent drawn against it. . . .

Boehringer Ingelheim Vetmedica, Inc., 68 F.Supp.2d at 551; *see also DaimlerChrysler AG*, 276 F.Supp.2d at 1063 (Intent inferred from "the fact that disclosing the existence of the litigation to the PTO would have entailed disclosing highly material information.").

V. ARGUMENT

A. Affymetrix Committed Inequitable Conduct By Failing to Disclose Litigation Which Was Highly Material to the Patentability of the '243 Patent With An Intent to Mislead the PTO.

Affymetrix failed to disclose the 4507 litigation with an intent to mislead the PTO. The mere existence of the 4507 litigation -- a litigation that asserted the invalidity and unenforceability of a direct ancestor patent with the same specification -- is material *per se* to the patentability of the claims of the '243 patent. MPEP § 2001.06(c) states that "[w]here the subject matter for which a patent is being sought is or has been involved in litigation, *the existence of such litigation and any other material information arising therefrom must be brought to the attention of the U.S. Patent and Trademark Office.*" (emphasis added).

As the 4507 litigation involved the basic subject matter of the '243 patent, the existence of the 4507 litigation was material *per se* to the patentability of the claims of the '243 patent.⁶ *DaimlerChrysler AG*, 276 F.Supp.2d at 1063 ("Section 2001 refers to 'the existence of the litigation and any other material information.' (emphasis added). Thus, under the MPEP, litigation is material *per se*."); *Nisus Corp. v. Perma-Chink Systems, Inc.*, 421 F.Supp.2d at 1104 ("'[R]elated litigation' is *per se* material information covered by the duty of disclosure."). The materiality of the 4507 litigation to the prosecution of the '243 patent is simply not a matter of dispute -- settled case law says it is material.

Even without this *per se* rule, the 4507 litigation was material to the prosecution of the '243 patent as the validity and enforceability of the '934 patent, which involves related subject matter to the '243 patent, was challenged in the 4507 litigation. *Boehringer Ingelheim*

⁶ Since the '243 patent is related to the '934 patent through a series of continuations and a divisional which share a common specification, the 4507 litigation involved the subject matter of the '243 patent and was required to be disclosed. See e.g., *DaimlerChrysler AG*, 276 F.Supp.2d at 1063 n.4.

Vetmedica, Inc., 68 F.Supp.2d at 551 ("The materiality of the concurrent [related patent] litigation which challenged both the validity and enforceability of the subject matter of the pending [related] application is obvious."); *DaimlerChrysler AG*, 276 F.Supp.2d at 1063 ("Moreover, in the prosecution of a continuation-in-part patent, the fact that the parent patent was the subject of litigation challenging its validity is clearly information that a 'reasonable [patent] examiner would consider [] important in deciding whether to allow the application to issue as a patent.'").

By failing to disclose the existence of the 4507 litigation, Affymetrix was able to conceal from the examiner, *inter alia*, the invalidity and inequitable conduct allegations that were made by Incyte and Synteni in the 4507 litigation.⁷ A reasonable examiner would undoubtedly have considered documents from the 4507 litigation, such as Incyte's Initial Disclosure of Prior Art (which details specific prior art references that anticipate or render obvious the claims of the '934 patent) (*See Ex. M*), and Incyte's and Synteni's motions⁸ regarding inequitable conduct during the prosecution of the '934 patent, to be highly material to the patentability of the claims of the '243 patent.

Affymetrix's intent to deceive the PTO by withholding this information is also quite clear from the factual record. Intent to deceive can be inferred where an applicant knew, or should

⁷ It is highly likely Affymetrix was aware of -- and yet still concealed -- many more damaging allegations and other similar information from the 4507 and 4508 litigations. However, the full extent of Affymetrix's inequitable conduct is difficult to determine because it refused to produce any of the documents from these prior litigations, and most of the motions filed in the 4507 and 4508 litigations were filed under seal. Illumina sought relief from this Court and requested that Affymetrix be ordered to produce the documents. Affymetrix refused to produce the documents, thus perpetuating its fraud.

⁸ There were several motions filed regarding inequitable conduct including, but not limited to, Incyte's Memorandum of Points and Authorities in Support of Motion For Leave to Add Additional Allegation of Inequitable Conduct, Incyte's and Synteni's Opposition to Affymetrix's Motion to Strike and Dismiss Certain Allegations of Inequitable Conduct, Reply in Support of Incyte's Motion For Leave to Add Additional Allegations of Inequitable Conduct to Its Second Amended 21165 Answer and Counterclaim.

have known, that the non-disclosed information would be material to the PTO's consideration of the patent application. *Critikon, Inc.*, 120 F.3d at 1256. As CEO of Affymetrix, Dr. Fodor signed Affymetrix's SEC filings wherein the 4507 litigation was discussed. (See Exs. B at 75, C at 88). As a member of Affymetrix's Board of Directors, Dr. Stryer signed the same SEC documents. (*Id.*) Mr. Norviel, Affymetrix's general counsel and a registered patent attorney, made many public statements as early as 1999 commenting on the litigation. (See Ex. S). Drs. Fodor and Stryer, who are inventors on both the '934 and '243 patents, knew (or should have known) that the 4507 litigation, with its allegations of inequitable conduct and invalidity relating to the '934 patent, was material to the prosecution of the '243 patent. Instead, Affymetrix provided the PTO two compact disks containing prior art and disclosed numerous, less relevant litigations and interference proceedings. This was clearly an attempt to misdirect the examiner with a "mountain of largely irrelevant data." *Rohm & Haas Co. v. Crystal Chem. Co.*, 722 F.2d 1556, 1572-73 (Fed. Cir. 1983).

The failure of Drs. Fodor and Stryer to disclose the existence of the 4507 litigation establishes the threshold showing of intent to deceive. *Boehringer Ingelheim Vetmedica, Inc.*, 68 F.Supp.2d at 551 ("The fact that [the patentee] did not provide the USPO, in writing, with the name of the pending case, its docket number, the district in which it was pending and this Court's conclusions, establishes a threshold showing of intent to deceive and a lack of good faith."); see also *DaimlerChrysler AG*, 276 F. Supp. 2d at 1063 (intent inferred from the fact that disclosure of the litigation would have entailed disclosing highly material information). Similar to the case in *Boehringer*, Drs. Fodor and Stryer failed to provide to the PTO in writing with the name, the docket number, the district in which the case was pending, and the Court's conclusions from the 4507 litigation during the prosecution of the '243 patent. Furthermore, as in *Boehringer*, Drs.

Fodor and Stryer failed to provide the PTO with the Court's opinions and a list of the parties' submissions from the 4507 litigation during the prosecution of the '243 patent. This conduct can only be explained by an intent to deceive.

Affymetrix's pattern of non-disclosure of the 4507 litigation is further evidence of its intent to deceive the PTO. *See e.g., Golden Valley Microwave Foods, Inc. v. Weaver Popcorn Co., Inc.*, 837 F.Supp.1444, 1471 (N.D. Ind. 1992) (finding intent to mislead based on applicant's "consistent repetitious effort to withhold information, which under normal circumstances would have been disclosed. . . ."). Affymetrix apparently understood that the duty of candor and good faith required the disclosure of litigation and any material information arising from such litigation. For example, several less material litigations (*i.e.*, those involving patents with a more attenuated connection to the '243 patent) were disclosed in the file history of the '243 patent. Why would Affymetrix disclose less relevant litigations, but not disclose the fact that a direct ancestor patent was also involved in litigation? Again, the only plausible answer is that Affymetrix possessed an intent to deceive.

Dr. Fodor's knowledge of the materiality of the 4507 litigation and his intent to deceive the PTO is further shown by his selective disclosure of the 4507 litigation and information from the litigation in other unrelated prosecutions.⁹ During the prosecution of the '506 patent -- a patent that is *not* a direct descendant of the '934 patent, but which lists Dr. Fodor as an inventor -- the existence of the 4507 litigation and Incyte's Initial Disclosure of Prior Art from that litigation *were disclosed* to the PTO. (*See* Exs. L and M). The fact that Dr. Fodor repeatedly failed to disclose the existence of the 4507 litigation in the file history leading up to the '243

⁹ Affymetrix clearly understood that prior litigation could be material to the PTO as shown by its disclosure of the 4508 litigation in the '143 and '625 patents' applications only after the PTO had issued notices of allowance. (*See* Exs. J and K).

patent, but did disclose the 4507 litigation in the file history of an unrelated patent, demonstrates his intentional pattern of deception meant to prevent the PTO from learning about the invalidity and inequitable conduct allegations from the 4507 litigation. *See e.g., Ferring B.V.*, 437 F.3d at 1191 ("in the absence of a credible explanation, intent to deceive is *generally inferred* from the facts and circumstances surrounding a knowing failure to disclose material information."). There is no reasonable explanation for this conduct, other than that Dr. Fodor intended to conceal the existence of the 4507 litigation and the allegations of invalidity and inequitable conduct regarding the '934 patent.

Affymetrix cannot escape its repeated attempts to misdirect and withhold material information from the PTO with a mere denial. *Critikon, Inc.*, 120 F.3d at 1257. This is especially true when the non-disclosed information is highly material. *Pharmacia Corp.*, 417 F.3d at 1373. Since the existence of the 4507 litigation is material *per se* and there is clear proof that Drs. Fodor and Stryer and Mr. Norviel knew of the allegations of invalidity and inequitable conduct relating to the '934 patent, they should have known that the 4507 litigation was material. Therefore, simply denying they acted with the intent to mislead the PTO will not negate the strong inference of intent raised against them by undisputed evidence.

The Court should find the '243 patent unenforceable as a result of Affymetrix's clear inequitable conduct in withholding the existence of the 4507 litigation from the PTO with an intent to deceive.

B. Affymetrix Committed Inequitable Conduct By Failing to Disclose the Pirrung Declaration Which Was Material to the Patentability of the '243 Patent With an Intent to Mislead the PTO.

Beyond not disclosing the existence of the 4507 litigation, Affymetrix intentionally withheld the highly material Pirrung declaration with the intent to mislead the PTO. "Materiality is not limited to prior art but embraces *any* information that a reasonable examiner would be

substantially likely to consider important in deciding whether to allow an application to issue as a patent." *Bristol-Myers Squibb Co. v. Rhone-Poulenc Rorer, Inc.*, 326 F.3d 1226, 1234 (Fed. Cir. 2003).

The Pirrung declaration, stating that the VLSIPS™ method (the same one disclosed in the specification of the '243 patent) could not be used to make nucleic acid arrays as of the 1990 timeframe, clearly meets this standard for materiality. The Pirrung declaration is a sworn statement by the lead inventor of the '243 patent that the specification of this patent, combined with the known teachings of the time, did not enable one of skill in the art as of 1990 to synthesize nucleic acids using the VLSIPS™ synthesis method. In the context of inequitable conduct, "whether a reference would be considered important by a reasonable examiner in determining whether a patent application is allowable, including whether the invention is enabled, is a separate issue from whether the invention is actually enabled." *Id.* at 1238-39. Therefore, it is irrelevant to this motion whether or not the Pirrung declaration actually establishes that the '243 patent is not enabled. A reasonable examiner would certainly consider Dr. Pirrung's opinions concerning the non-enablement of the VLSIPS™ method important in deciding whether to allow the '243 patent to issue, especially considering that Affymetrix specifically argued that this method allowed them to make the high density arrays that the prior art allegedly could not.

The Pirrung declaration is also material under 37 C.F.R. § 1.56(b)(ii) as a statement that refutes, or is inconsistent with, a position that Affymetrix took in asserting an argument of patentability. In prosecuting the '243 patent, Affymetrix took the position that the VLSIPS™ method to manufacture high density nucleic acid arrays was enabled, and claims priority to March 7, 1990. However, Pirrung's declaration states that the VLSIPS™ method could not be

used in this manner in the 1990 time frame. Pirrung's declaration cannot be reconciled with the position that Affymetrix took to obtain allowance of the '243 patent claims. At the very least, the declaration was material and the patent examiner should have been given an opportunity to consider this document that presents a position that is 180 degrees opposite to the position that was taken during prosecution. *See e.g., Research Corp. Technologies, Inc. v. Microsoft Corp.*, No. CV-01-658-TUC-MLR, 2006 WL 1544381 at * 1 (D. Ariz. May 22, 2006) (finding intent to deceive when applicants failed to disclose their test results which contradicted their previous assertions regarding the patentability of their claims to the PTO); *Bristol-Myers Squibb Co.*, 326 F.3d at 1234, 40 (finding intent to deceive where the applicant was "intimately familiar with" an article written by his co-inventors contradicting claims regarding "specific protecting groups" in the invention, but failed to disclose the article).

Affymetrix's intent to deceive can be inferred where Affymetrix must have known that the Pirrung declaration would be material to the PTO's consideration of the patent application. *Critikon, Inc.*, 120 F.3d at 1256. There can be no dispute that Affymetrix was aware of the Pirrung declaration. In fact, Affymetrix specifically required the redaction of the most damaging portions of the Pirrung declaration during the 4508 litigation, demonstrating an intimate knowledge of -- and its intent to hide -- the contents of this document. (*See Ex. O*). Moreover, prior to the filing of the '243 patent, *each* of the other three inventors of the '243 patent -- Dr. Lubert Stryer, Dr. J. Leighton Read and Dr. Stephen Fodor -- admitted in declarations, under oath, that they had read the Pirrung declaration.¹⁰ As Affymetrix and each inventor of the '243 patent had an intimate knowledge of the contents of the Pirrung declaration, there can be no

¹⁰ The '243 patent was filed on March 15, 2002. Fodor's declaration in which he admits to having seen the Pirrung declaration is dated October 12, 2000. (*See Ex. T*). Read's declaration in which he admits to having read the Pirrung declaration is dated October 30, 2000. (*See Ex. U*). Stryer's declaration in which he admits to having read the Pirrung declaration is dated March 6, 2002. (*See Ex. V*).

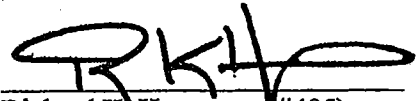
doubt that this declaration was withheld from the PTO with an intent to deceive. *Bristol-Myers Squibb Co.*, 326 F.3d at 1234, 40.

The evidence clearly shows that Affymetrix intentionally withheld the Pirrung declaration, which was highly material to (and in fact completely undermines) the patentability of the '243 patent, with an intent to mislead the PTO. This Court should find the '243 patent unenforceable as a matter of law.

VI. CONCLUSION

For the foregoing reasons, Illumina respectfully requests that the Court enter summary judgment of unenforceability of the '243 patent due to Affymetrix's inequitable conduct during the prosecution of the '243 patent.

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CERTIFICATE OF SERVICE

I hereby certify that on the 27th day of July, 2006, I caused to be electronically filed the foregoing document, **REDACTED VERSION OF OPENING BRIEF IN SUPPORT OF ILLUMINA'S MOTION FOR SUMMARY JUDGMENT OF INEQUITABLE CONDUCT AND UNENFORCEABILITY OF U.S. PATENT NO. 6,646,243** with the Clerk of the Court using CM/ECF which will send notification of such filing to the following:

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Additionally, I hereby certify that on the 27th day of July, 2006, the foregoing document was served via email on the above and on the following non-registered participant:

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